JUN 20 2008

FLOWCARDIA, INC.

5) 510(k) Summary

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number K080765

FDA CDRH DMC

MAR 18 2008

Received

Applicant Information

Date Prepared:	**March 17, 2008**
Name and Address:	**FlowCardia, Inc.** **745 N. Pastoria Avenue** **Sunnyvale, CA 94085** **Ph: (408) 617-0352**
Contact Person:	**Dustin Michaels, Vice President of CR/QA/RA** **Ph: (408) 617-0352 x302** **Fax: (408) 617-9198**

Device Information

Classification:	**DQY**
Trade Name:	The CROSSER LP System
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Device

The CROSSER System manufactured by FlowCardia, Inc. (K062868)

Device Description

The CROSSER System consists of a re-usable electronic Generator, Foot Switch, high-frequency Transducer, and single-use CROSSER LP Catheter.

Each Catheter is connected to the electronic Generator through the Transducer. The Foot Switch is used to activate the system. The Generator and Transducer convert AC power into high-frequency mechanical vibrations which are propagated through a Nitinol core wire to the stainless steel tip of the CROSSER LP Catheter. The main body of the catheter is constructed from Pebax and a hydrophilic coating which covers the distal end of the catheter.

K080705

Technological Characteristics

The FlowCardia CROSSER LP System is substantially equivalent to the predicate device. The predicate and CROSSER LP System catheters are substantially equivalent with respect to materials, design construction and performance. Both devices are indicated for use in coronary chronic occlusions. Both utilize the same CROSSER Electronics for operation. The main difference between the two devices is the diameter of the distal tip. The CROSSER LP has a 0.6mm distal tip while the predicate device has a 1.1mm tip.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia CROSSER LP System met the acceptance criteria and performed similarly to the predicate device. In addition to dimensional verification, the following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/Integrity, Biocompatibility, Bench top Simulated Efficiency, Catheter Fatigue Testing, Shelf Life and Package Integrity Testing. Animal studies were conducted with the CROSSER LP to establish initial safety and performance.

Conclusion

Based upon device physical comparisons the CROSSER System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 2008

FlowCardia Inc.
c/o Mr. Dustin Michaels
Vice President of CR/QA/RA
745 N. Pastoria Avenue
Sunnyvale, CA 94085

Re: K080765
Trade Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1330
Regulation Name: Cather Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: March 17, 2008
Received: March 18, 2008

Dear Mr. Michaels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K080765

Device Name: **The CROSSER LP System**

Indications for Use:

The CROSSER LP System is indicated in coronary arteries to facilitate the intra-luminal placement of conventional guidewires beyond chronic total occlusions.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devic
510(k) Number K080765